PATENT COOPERATION TREATY

REC'D 0 4 JUL 2005

from the		WIPO PC
NTERNATIONAL SEARCHING AUTHOR	ITY	
To: W. THAD ADAMS III ADAMS EVANS P.A.		PCT TRITTEN OPINION OF THE
2180 TWO WACHOVIA CENTER CHARLOTTE, NC 28282	INTERNAT	IONAL SEARCHING AUTHORITY
		(PCT Rule 43bis.1)
_	Date of mailing (day/month/year	9 4 0 0
Applicant's or agent's file reference	FOR FURTHE	See paragraph 2 below
2765/251PCT International application No.	International filing date (day/month/year)	Priority date (day/month/year)
Thernauous approach	14 February 2005 (14.02.2005)	31 March 2004 (31.03.2004)
PCT/US05/04454 International Patent Classification (IPC) or	both national classification and IPC	
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IPC(7): A61F 5/00 and US Cl.: 602/8 Applicant		
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BSN MEDICAL, INC.		
1. This opinion contains indications rela	ting to the following items:	,
Box No. I Basis of the	opinion	·
Box No. II Priority	to another i	aventive step and industrial applicability
Box No. III Non-establi	shment of opinion with regard to novelty, i	it Activity of 210b min management 1.1
Box No. IV Lack of uni	y of invention	
Box No. V Reasoned s applicabilit	vatement under Rule 43 <i>bis</i> .1(a)(i) with rega y; citations and explanations supporting suc	rd to novelty, inventive step or industrial ch statement
Box No. VI Certain doc	uments cited	
Box No. VII Certain def	ects in the international application	
Box No. VIII Certain ob	ervations on the international application	
International Preliminary Examine	ninary examination is made, this opinion ig Authority ("IPEA") except that this the IPEA and the chosen IPEA has notifi ional Scarching Authority will not be so co	will be considered to be a written opinion of the does not apply where the applicant chooses an ed the International Bureau under Rule 66.1 bis(b) onsidered.
If this opinion is, as provided about the interpretation of Form PCT/ISA/220 or before the	re, considered to be a written opinion of the reappropriate, with amendments, before the expiration of 22 months from the priority	the IPEA, the applicant is invited to submit to the
For further options, see Form PCT/	isA/220.	
3. For further details, see notes to For		
Name and mailing address of the ISA/	S Authorized	otticer 12
Mail Ston PCT, Attn: ISA/US	Kim M. Le	wis Much from
Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	Telephone)	No. (571)272-4395

Facsimile No. (703) 305-3230
Form PCT/ISA/237 (cover sheet) (January 2004)

International application No.
PCT/US05/04454

Box No	I Basis of this opinion
was fi	egard to the language, this opinion has been established on the basis of the international application in the language in which it led, unless otherwise indicated under this item. This opinion has been established on the basis of a translation from the original language into the following language which is the language of a translation for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With a	regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed tion, this opinion has been established on the basis of:
a.	type of material
	a sequence listing
	table(s) related to the sequence listing
b.	format of material
	in written format
	in computer readable form
. с.	time of filing/furnishing
	contained in international application as filed.
	filed together with the international application in computer readable form.
	furnished subsequently to this Authority for the purposes of search.
3.	In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been file or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4 Ada	litional comments:
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Form PCT/ISA/237(Box No. I) (January 2004)

International application No. PCT/US05/04454

Box No. V Reasoned statement under Rule	e 43 <i>bis.</i> 1(a)(i) with regard to novelty, inventive step or industrial lanations supporting such statement
applicability; citations and expi	difference and because
Statement Novelty (N)	Claims 8 and 13 YES Claims 1-7 and 9-12 NO
Inventive step (IS)	Claims 8 and 13 YES Claims 1-7 and 9-12 NO
Industrial applicability (IA)	Claims 1-13 YES Claims NONE NO

2. Citations and explanations:

Claims 1-13 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent No. 6,488,642 ("Darcey") in view of U.S.

Patent No. 6,280,815 ("Ersfeld et al").

Regarding claims 1, 3, 5, 9 and 10, Darcey substantially discloses all the claimed features. More specifically, Darcey discloses, a medical bandaging product in roll form for being dispensed in predetermined lengths suitable for a given medical use, and comprising an elongate sleeve formed of moisture-impervious material and scalable to prevent entry of moisture, and an elongate medical bandage material substantially the same length as the sleeve and sealed therein against entry of moisture until use, the medical bandage material comprising, a substrate (16), a reactive system impregnated into or coated onto the substrate and remaining stable when maintained in substantially moisture-free conditions and hardening upon exposure to sufficient moisture to form a rigid, self support structure (col. 8, lines 21-25). Darcey also discloses padding (tubular wrapping 18 at col. 7, lines 26-33) and resealing means for resealing the sleeve against entry of moisture after a predetermined length of the bandage material has been dispensed from the sleeve for use to prevent hardening of the substrate of the bandage material remaining in the sleeve (col. 8, lines 21-25).

Darcey fails to teach that the substrate comprises a foam layer, that the foam is polymer foam and that the substrate includes a textile reinforcement layer. However, Ersfeld et al. disclose a substrate comprising a polymer foam (52) and textile reinforcement layers (54, 56). The foam is impregnated with a hardenable (setting) resin as a means by which a custom shoe insert is made.

In view of Ersfeld et al., it would have been obvious to one having ordinary skill in the art to substitute the materials of construction for substrate (16) of Darcey for the materials of construction of substrate (50) of Ersfeld et al. as an obvious alternative since it appears that both substrates perform the same function.

Regarding claim 2, note col. 8, lines 9-14.
Regarding claim 4, note the table in col. 7, which discloses the formulation of the reaction system

Regarding claim 6, note Fig. 14 and col. 5, line 60-col. 6, line 14.

Regarding claim 11, the method as claimed is inherently practiced when the modified device of Darcey (see the discussion of

Regarding claim 12, Darcey discloses a package comprising an elongate sleeve (13) ad the medical material is generally the claim 1 above). same length as the sleeve. Further, disclosed in the inherent step of positioning the bandage material within the package comprises the step of placing the bandage material within the sleeve such that the bandage material extends along the length of the sleeve in a single layer (Fig. 1).

Claims 8 and 13 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest that some of the fibers from the textile reinforcement layer penetrate into the foam layer for providing rigidity and stability.

Claims 1-13 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

International application No.

PCT/US05/04454

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Dov No. V	т	Certain	defects	in '	the	international	applica	HOH

The following defects in the form or contents of the international application have been noted:

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof: Page 8, para. [0036], line 4, "14" should read -13-.

Form PCT/ISA/237 (Box No. VII) (January 2004)

PATENT COOPERATION TREATY

REC'D 0 4 JUL 2005

PCT WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing 3 0 JUN 2003. FOR FURTHER ACTION See paragraph 2 below day/month/year) Priority date (day/month/year) 2005) 31 March 2004 (31.03.2004) See paragraph 2 below					
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and industrial applicability					
gard to novelty, inventive step and industrial applicability					
Box No. IV Lack of unity of invention					
Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement					
Box No. VI Certain documents cited					
Box No. VII Certain defects in the international application					
oral application					
de, this opinion will be considered to be a written opinion of the except that this does not apply where the applicant chooses an IPEA has notified the International Bureau under Rule 66.1 bis(b) will not be so considered.					
itten opinion of the IPEA, the applicant is invited to submit to the dments, before the expiration of 3 months from the date of mailing from the priority date, whichever expires later.					
Authorized officer					
Kim M. Lewis Muthaufur					
Telephone No. (571)272-4395					
in it					

Form PCT/ISA/237(Box No. I) (January 2004)

International application No.
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	Tallasmos sees 4
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4. Add	itional comments:
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WRITTEN OPINION OF THE

International application No. PCT/US05/04454

WRITTEN OPINION OF INTERNATIONAL SEARCHING	AUTHORITY	FC1/0503/04134
Box No. V Reasoned statement under Rule applicability; citations and expla	43 his 1(a)(i) with rega	rd to novelty, inventive step or industrial h statement
1. Statement		YES
Novelty (N)	Claims 8 and 13	NO
-	Claims 1-7 and 9-	-12
	Claims 8 and 13	YES
Inventive step (IS)	Claims 1-7 and 9	-12NO
	Clantis 17 due 2	
The state of the s	Claims 1-13	YES
Industrial applicability (IA)	Claims NONE	No
\ \		
2. Citations and explanations:		over U.S. Patent No. 6,488,642 ("Darrey") in view of U.S.
Regarding claims 1, 3, 5, 9 and 10, Darce discloses, a medical bandaging product in roll form comprising an elongate sleeve formed of moisture-medical bandage material substantially the same lebandage material comprising, a substrate (16), a rewhen maintained in substantially moisture-free co support structure (col. 8, lines 21-25). Darcey also for resealing the sleeve against entry of moisture sleeve for use to prevent hardening of the substrate Darcey fails to teach that the substrate textile reinforcement layer. However, Ersfeld et alayers (54, 56). The foam is impregnated with a In view of Ersfeld et al., it would have I construction for substrate (16) of Darcey for the resince it appears that both substrates perform the same at the properties of Regarding claim 2, note col. 8, lines 9-Regarding claim 4, note the table in col Regarding claim 6, note Fig. 14 and con Regarding claim 17, note dispenser (11) Regarding claim 11, the method as claim 1 above). Regarding claim 12, Darcey discloses same length as the sleeve. Further, disclosed in step of placing the bandage material within the slayer (Fig. 1). Claims 8 and 13 meet the criteria set out in PCT	by substantially discloses all for being dispensed in pre- impervious material and search as the sleeve and seal stactive system impregnated additions and hardening upon discloses padding (tubula after a predetermined length to omprises a foam layer, that all disclose a substrate compardenable (setting) resin as been obvious to one having materials of construction of ame function. 14. 1. 7, which discloses the foat 1. 5, line 60-col. 6, line 14. 1. med is inherently practiced a package comprising an el the inherent step of position leeve such that the bandage article 33(2)-(3), because rate into the foam layer for	If the claimed features. More specifically, Dates, and edetermined lengths suitable for a given medical use, and calable to prevent entry of moisture, and an elongate led therein against entry of moisture until use, the medical into or coated onto the substrate and remaining stable on exposure to sufficient moisture to form a rigid, self or wrapping 18 at col. 7, lines 26-33) and resealing means he of the bandage material has been dispensed from the remaining in the sleeve (col. 8, lines 21-25). If the foam is polymer foam and that the substrate includes a prising a polymer foam (52) and textile reinforcement is a means by which a custom shoe insert is made. It is a cordinary skill in the art to substitute the materials of it is substrate (50) of Ersfeld et al. as an obvious alternative formulation of the reaction system. If when the modified device of Darcey (see the discussion of longate sleeve (13) ad the medical material is generally the material extends along the length of the sleeve in a single of the private of the stream of th

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Box No. VII Certain defects in the international application	11

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